c.) Remarks

Claim 9 has been amended in order to recite the features of claim 16. Accordingly, claims 2-5 and 16 have been cancelled as superfluous. The subject matter of the amendment may be found in the specification as filed from page 7, line 22 to page 8, line 13, as well as in original claim 8. Accordingly, no new matter has been added.

Claims 2-5, 9-12 and 16 are rejected under 35 U.S.C. §112, first paragraph, because the Examiner states the present invention does not enable prevention of higher brain function impairment. Although this basis of rejection is respectfully traversed in view of the showings of record, solely in order to reduce the issues and expedite prosecution, Applicants have above amended claim 9 to delete "preventing and/or", without prejudice or disclaimer.

Claims 2-5, 9-12 and 16 are rejected under 35 U.S.C. §103(a) as being unpatentable over Shimada (EP 1 016 407) in view of Ikeda (*Behavioral Brain Research*, Vol. 118 (2001) 17-25).

In support of this rejection, the Examiner states Shimada shows (E)-8-(3,4-dimethoxystyryl)-1,3-diethyl-7-methylxanthine (hereinafter "KW 6002") is effective for treating various neurodegenerative disorders such as brain ischemia, but not higher brain dysfunction. Ikeda is cited for the proposition that brain ischemia results in learning and memory impairment. Thus, the Examiner contends it would have been obvious, in view of Ikeda, to utilize Shimada's KW 6002 to treat higher brain function impairment.

This rejection is respectfully traversed. Prior to setting forth their bases for traversal, however, Applicants would briefly like to discuss the salient features of the present invention and *inter alia* its patentable nature over the prior art.

As the Examiner is well-aware, the present invention relates to treating higher brain dysfunction (namely impairment of memory, thinking, recognition, action or learning) caused by head trauma, by administering KW-6002.

Shimada teaches that KW-6002 is effective for treating neurodegenerative disorders such as Alzheimer's disease, propagating spongy brain fever, brain ischemia[1] and the like. However, these disorders are not related to *head trauma*, as recited in the pending claims (see claim 9, line 2). Indeed, even though Ikeda teaches that brain damage produced by hypoxia-ischemia resulted in long-lasting learning and memory impairment, hypoxia-ischemia also is not related to head trauma.

In contrast, the subject matter of the present invention is explicitly directed to a method of treating higher brain function impairment caused by brain injury due to head trauma, which subject matter is not at all associated with brain ischemia or the other disorders described in the prior art. Therefore, respectfully submitted, the Examiner has not made out a *prima facie* case of obviousness of the claims as presently-amended. Accordingly, this rejection is overcome and should be withdrawn

Claims 2-5, 9-12 and 16 are rejected on the ground of nonstatutory obviousness-type double patenting over claim 1 of U.S. Patent No. 7,115,614 in view of Ikeda, as well as over claims 1-3 of U.S. Patent No. 6,727,259. For the Examiner's convenience, both these patents are family member equivalents of Shimada EP 1 016 407 discussed above. Accordingly, these rejections should be withdrawn for the foregoing reasons as well.

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[1] As discussed, however, only brain ischemia is relevant herein, in view of the teachings of Ikeda.

In view of the above amendments and remarks, Applicants submit that all of the Examiner's concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 9-12 remain presented for continued prosecution.

Applicants' undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

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